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By: _____ Date: November 29, 2004
William J. Sapone

File No. 747/9-1647

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant : Thomas Frederick ENNS Conf. No.: 7543

Serial No. : 10/067,511 Group Art No.: 3763

Filed: February 4, 2002 Examiner: Mathew F. DeSanto

For: : DRUG DELIVERY NEEDLE DEVICE

Board of Patent Appeals and Interference
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Sir:

Enclosed herewith is an Appeal Brief, Appendix A, Appendix B and a check in the amount of $170.00 for the appeal brief fee for the above-referenced application.

Respectfully submitted,

_____
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APPEAL BRIEF

This is an Appeal by the applicant from the Final Office Action dated May 5, 2004 finally rejecting claims 1, 3, 4, 6, 7, 8, 9, 11, 12, 14, 15 and 16 of the above identified application. The appealed claims appear in Appendix A.

Real Party In Interest

The real party in Interest is Benlan, Inc, the owner by way of assignment of all right title and interest to the above referenced patent application from the inventor, Thomas Frederick Enns.

Related Appeals And Interferences

There are no related appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

Status Of Claims

Claims 1-16 were originally in the application. Claims 2, 5, 10 and 13 were cancelled. Claims 1, 3, 6, 11 and 15 were amended during prosecution. Claims 4, 7-9, 12, 14 and 16 are as originally filed. Claims 1, 3, 4, 6-9, 11, 12 and 14-16, presented in Appendix A, remain in the case, are pending, rejected and are the subject of this appeal.

Status Of Amendments

No amendment was made subsequent to the Final Office Action dated May 5, 2004.

Summary Of Claimed Subject Matter

The claims are directed to drug delivery needle device for percutaneous injection of a drug into an implanted drug delivery device that includes a catheter for drug delivery to a patient. (Spec. p.1, l. 5-7) Conventional drug delivery needles include a right angle bend for access to a drug holding chamber, and are designed to inhibit septum coring while assuring penetration of the skin and septum at an angle of approximately 90 degrees. (Spec. p.1, l. 23-28) An angled portion of the needle lies approximately parallel with the surface of the skin to facilitate taping to the patient. (Spec. p.1, l. 28-30)

A problem with the prior art needle devices is that they are difficult to hold and push through the skin and septum, since the physician must firmly grasp the needle to drive it through. Taping of the prior art device also limits air flow around the wound, and can contribute to infection. (Spec. p.1, l. 31-p.2, l. 2)

The applicants invention solves these problems. Claim 1 specifies a specific arrangement of components, including a base, a spacer above the base, one end of which is integral with the base, a pair of opposed flexible handles integral with a second end of the spacer, and, a rigid spine located above the spacer and handles. The rigid spine includes the angled [first] portion of the L-shaped needle therein. The opposed flexible handles have distal ends that are movable into contact with each other and the rigid spine when the handles are grasped, providing a firm grip for insertion and withdrawal.

The inventive device is illustrated with reference to Fig. 2. The device 20 has handles 38, 39 attached to an upper end 46 of a spacer 36, that at its lower end 44 is integral with a base 34. A cover 40 contains a first portion 24 of the needle 30, which together form a spine 48 located above the handles. The handles are thus spaced away from a wound site and can be taped down when the needle is inserted into the patient, while still permitting air flow around the entry location, as shown in Fig. 3. Note the needle and cover form the rigid spine 48, located above the handles 38, 39, which reduces the overall size of the device.

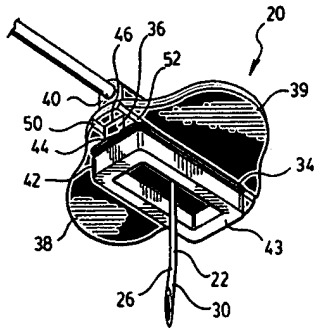


FIG. 2.

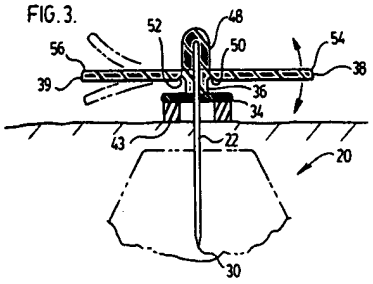


FIG. 3.

As shown in Fig. 6, when in use, the handles are grasped by pinching the handles together such that the ends of the handles move into contact with each other and are supported by the rigid spine that includes a portion of the needle therein to provide support and accuracy during insertion of the needle. This corresponds to the language of claim 1, where, "a pair of opposed flexible handles [38, 39] integral with said second end [46] of said spacer [36], the flexible handles adapted to be grasped for insertion of said needle device into and removal of said needle device from said patient, a rigid spine [48] located above the spacer and the handles, ...the handles having distal ends movable into contact with each other when the handles are grasped, the handles engaging said spine when said distal ends are in contact".

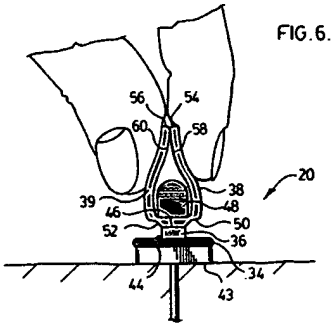


FIG. 6.

Grounds Of Rejection To Be Reviewed On Appeal

There is only one rejection to be reviewed on appeal. The issue for decision is whether claims 1, 3, 4, 6, 7, 8, 9, 11, 12, 14, 15 and 16 are anticipated under 35 U.S.C. §102(b) by German Patent DE 4426784 to Lusson ("Lusson"), a translation of which was provided by the applicant to the examiner in a response submitted on February 9, 2004. A copy is enclosed in Appendix B.

ARGUMENT

I. Claim 1 Is Not Anticipated By Lusson.

A. Legal Standard

A finding of anticipation requires that the cited document describe all of the elements of the claims, arranged as in the patented device. Shearing v. Iolab Corp., 975 F.2d 1541, 1544-45, 24 U.S.P.Q. 2d 133, 1136 (Fed. Cir. 1992); Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989); Perkin-Elmer Corp v. Computervision Corp., 732 F.2d 888, 894, 221 U.S.P.Q. 669, 673 (Fed. Cir. 1984). C.R. Bard, Inc. V. M3 Sys., Inc., 157 F.3d 1340, 1349 (Fed. Cir. 1998). In addition, the reference must be enabling, thus placing the allegedly disclosed subject matter in the possession of the public. In re Spada 15 U.S.P.Q 2d 1655 (Fed. Cir. 1990).

In this case, the test for anticipation is not met. The cited reference fails to contain all the elements of the claimed invention, and fails as well to have placed the invention in the possession of the public. One skilled in the art, viewing the cited reference would not find each and every element of the applicants' invention, and would in fact be led away from it.

B. The Prior Art

Lusson discloses a perfusion apparatus for injection of a drug into an implanted drug delivery device having a catheter for drug delivery to a patient, designed to "avoid any risk of being stuck by the perfusion needle".(Lusson, p.2, l. 17-19). With reference to Fig. 1, a first embodiment includes a base 18, a feed conduit 12 entering a side of the base, a needle 10 extending from a bottom of the base. The feed conduit and needle extend through the base.

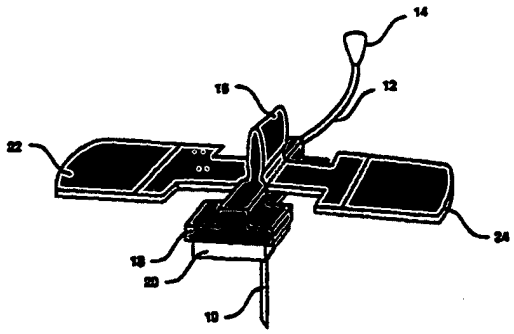


FIG. 1

A pair of wings 22, 24 extend from an upper portion of the base 18, with a grip 16 located above the wings. It is the grip which is used for grasping with the thumb and forefinger in order to insert the needle and withdraw the needle from the patient. (Lusson, p. 4, l. 3-6).

The two wings are oppositely aligned when the needle is inserted into the septum, and are hinged to the body so that the needle may be pulled out by pressing downwardly on the wings. (Lusson, P. 4, l. 18-24) The two wings end up in a downwardly folded position, with the needle protected therebetween, as shown in Fig. 2. The ability to downwardly fold is critical to Lusson: "...the caregiver undergoes no risk of being stuck unwillingly by the needle, because the fingers, including the thumb are protected constantly by the wings." (Lusson, p. 5, l. 1-7) The wings thus function as needle shields, which fold together around the needle. Llines of weakness 26 divide the wings into one or more flaps, to facilitate this function. (Lusson, p. 5, l. 8-12)

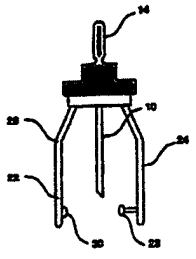


FIG. 2

In a second embodiment, shown in Fig. 3, Lusson utilizes a pair of circularly curved elements 40 and 42 that maintain the wings in a downwardly oriented position: "...the wings 44, 46 each have two parts 52, each of which overlaps the edge of the corresponding circularly curved elements 40, 42. When the wings are in the position shown in Figure 3 and 4, they are maintained in this position. Thereby they define a specific angle (for example about 35°) with the horizontal, due to the fact that the circularly curved elements prevent the wings from taking a horizontal position". (Lusson, p. 6, l. 8-12) As in the Fig. 1 embodiment, the needle terminates in the base, below the wings. Again, there is a separate finger grip 36.

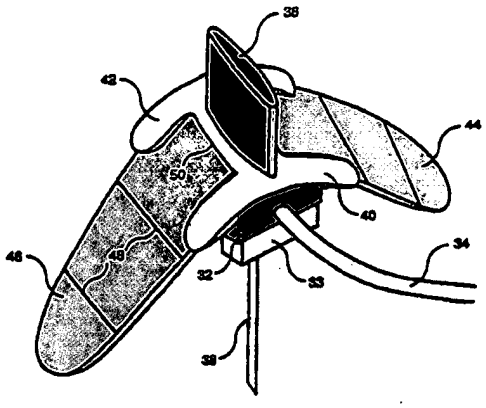


FIG. 3

C. The Claimed Invention Is Not Anticipated

Applicants' claim 1 requires a specific arrangement of components, including, from bottom to top, a base, a spacer, one end of which is integral with the base, a pair of opposed flexible handles integral with a second end of the spacer, and a rigid spine located above the spacer, which is defined as including a first portion of the L-shaped needle therein. The opposed flexible handles have distal ends that are movable into contact with each other when the handles are grasped, engaging the spine when the distal ends are in contact.

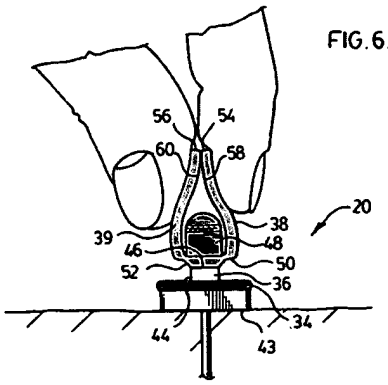


FIG. 6.

Lusson has a completely different structure and as such, fails to describe each and every element of claim 1 as required for anticipation. Lusson has no rigid spine located above a spacer and a pair of opposed handles, and including a first portion of the L-shaped needle therein. Instead, Lusson has a device in which the needle terminates within the base. The base has a pair of needle shields, attached to the base, and a separate handle or grip.

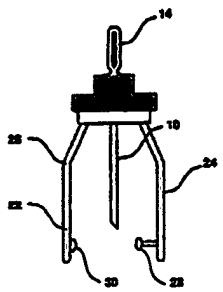


FIG. 2

The Examiner has given no effect to the specific wording of claim 1, which requires a "rigid spine" formed integrally with a "spacer", the needle having a "first portion" in the "spine". The defined spacer must have first and second ends that are spaced apart, the first end integral with the base and the second end integral with a pair of opposed flexible handles. Thus, the spacer must necessarily end at the opposed flexible handles, and be located under the opposed flexible handles, and the rigid spine must be located above the spacer and the handles, to meet each and every element of claim 1.

In referring to Lusson, the Examiner equated the base with the spacer of claim 1. However, then the base 32 must have a first end and a second end longitudinally spaced from the first end, and a pair of opposed flexible handles must be integral with the second end of this alleged spacer. Since the Examiner equates the shielding wings with the opposed pair of flexible handles, the spacer must end at these wings. Thus, the spacer cannot extend past the wings. Further, a rigid spine must also be located above the spacer and must include a first portion of the L-shaped needle therein. The grip in Lusson does not meet the spine limitation, as there is no portion of the L-shaped needle therein.

If one argues as the Examiner has that the spine and the spacer are integrally formed and therefore those elements are a single piece, there cannot possibly be an end of a spacer in Lusson that is integral with a pair of opposed flexible handles, as claimed. Rather, the shielding wings extend from a central portion of what the Examiner asserts is the unitary spine and spacer element. This clearly differs from claim 1 which requires an opposed pair

of flexible handles to be integral with an end of the spacer, and a distinct rigid spine structure.

The applicants' claimed invention is distinguished by the recited claim elements and their orientation. When the ends of the handles are in contact with each other (when grasped), the handles engage the spine. Since the rigid spine is located above the spacer and the handles, the handles must necessarily move upwardly to grasp the rigid spine that is located above the handles. When not in use, the flexible handles can be taped down to the patient, the handles spaced from the insertion point by the spacer to permit air flow and limit infection.

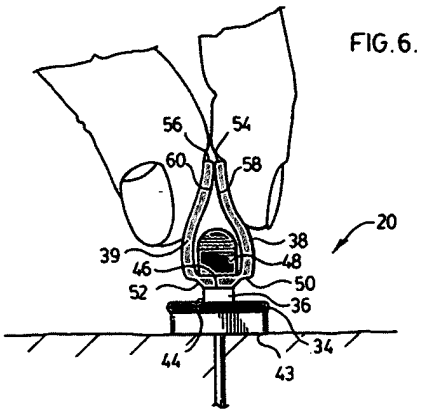


FIG.6.

When taped to the patient, the rigid spine protrudes only slightly upward, that is, it is a compact and nearly planar structure, as compared to Lusson, which has the upward projecting finger grip which must be large enough to grasp safely with the fingers. In the applicants' device, the rigid spine is not required to be large enough to be grasped for inserting the needle device or removing the needle device from the patient, as clearly illustrated in Fig. 6. It is the handles that are grasped, the handle ends moved upwardly into contact with each other and the rigid spine when grasped, providing good finger support during needle insertion for assuring accuracy and control.

Note also that the handles are shorter that the wings of Lusson. They are not longer than the needle, as shown in Fig. 6. This is because they are not shielding wings. Lusson requires that the wings be longer than the needle to fulfill the shielding function. (Lusson p. 5, l. 17) This is clearly shown in Lusson Figs. 1, 2 and 3.

A side by side comparison is illustrative. Below is shown the applicants device, the rigid spine 48 "located above the spacer [36] and the handles [38, 39], the rigid spine including a first portion of said L-shaped needle therein" (claim 1).

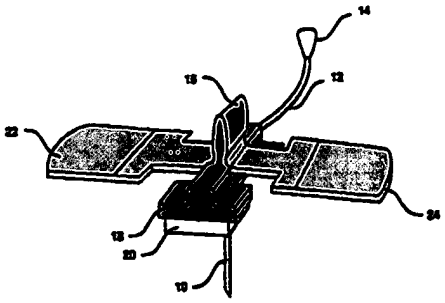
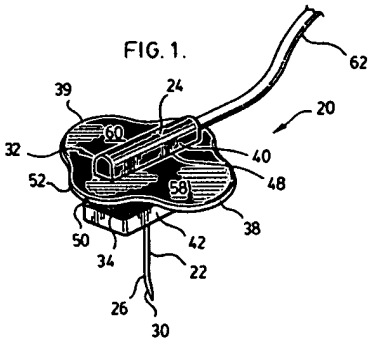


FIG. 1



Lusson, on the other hand, has no such rigid spine. Wings are attached to the base, which itself receives the upper portion of the right angle needle. The wings are thus above the needle. The grip 16 is not a "rigid spine" as called for in claim 1, and the wings do not form a handle for insertion or withdrawal, rather they are moved together to enclose the needle, to prevent needle sticks. One would certainly not use the wings closed around the needle as a handle, for fear of a needle stick.

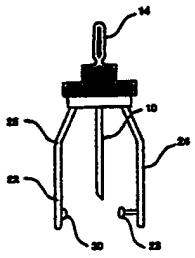
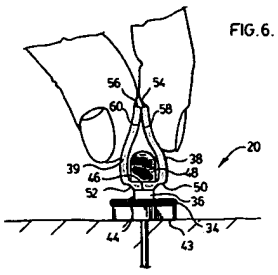


FIG. 2



The specific elements and their arrangement are important to achieving the results of the invention. Lusson has a device with wings which must be movable downwardly, to envelope the needle, having a separate distinct handle 16. Specific curved structures are even provided in the embodiment of Figure 3 to prevent any upward movement. These wings cannot possibly be moved into contact with each other to engage a rigid spine located above the handles as defined in applicants' claim 1, and to do so would be contrary to Lusson.

The rigid spine of the applicants invention enables a solid grip of the upper end of the needle portion with the handles during insertion and withdrawal, the fingers spaced away from the needle end. On the other hand, pressing downwardly on the wings of Lusson during withdrawal to move the wings into proximity with the needle, (the key advantage of Lusson stated on p. 5, l. 1-4), provides virtually no grip on the needle itself, as the wings move inwardly over the skin of the patient towards each other as the needle is withdrawn, which additionally also brings the fingers into close proximity to the needle tip.

The wings of Lusson are not handles, nor are they constructed to move upwardly. The fact that these are hinged does not mean that they are free to swing either way, and even if they were, that would make no difference in the analysis, as each and every claimed element must be found, arranged as in the claimed invention to anticipate, and that is not the case here.

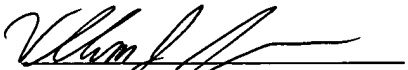
There is no "rigid spine" which includes a portion of the L-shaped needle therein. The wings are not "handles" which engage a "rigid spine" located above the "handles". There are no "handles" located above a "spacer", located a base, as required by claim 1. Every element, not just one or two must be present to anticipate. Relative to enablement, the wings are not disclosed for grasping, but instead, are shields which move downwardly to cover the end of the needle when the device is removed from the patient, a separate grip provided as the handle.

As each element of the claim 1 is not found in Lusson, there can be no anticipation, and the rejection of claim 1 and the depending claims must be reversed.

CONCLUSION

For the above noted reasons, claim 1, and the claims depending therefrom are novel and reversal of the rejection and allowance of the application is respectfully requested.

Respectfully submitted,



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